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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,618	04/16/2004	Jian Cao	P-21057.00	1313

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MEDTRONIC, INC.
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EXAMINER

KAHELIN, MICHAEL WILLIAM

ART UNIT	PAPER NUMBER
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3762

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/826,618

Applicant(s)

CAO ET AL.

Examiner

Michael Kahelin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 10/4/2006 with respect to claims 1-23 have been fully considered but they are not persuasive. Applicant argued that Kim et al. (2002/0183637, hereinafter "Kim") fails to disclose updating a template using only the collected second events in response to the template not being valid because, as shown in Fig. 6, the 16 template-generation beats are a distinct set of beats from the 21 beats acquired to determine fiducial point polarity or the beats used to determine template correlation. As evidence, Applicant referred to paragraph 82 of Kim's disclosure, namely the phrase, *"...the currently stored template features are checked 522 prospectively with newly detected template beats. This is a beat-by-beat operation, and there is no need to store multiple beats."*

2. Kim is still considered to anticipate the claimed subject matter based on a broad interpretation of "second selected events". The Examiner's interpretation of "first selected events" are the events used to construct the initial template. The "second selected events" are events following the first selected events (i.e. from initial template generation to the far right of Fig. 6, namely "Natural end of Template Update"). Although there are certain sub-sets of these "second selected events" including the events used to test the template correlation, compute fiducial point polarity, and redefine a template (as indicated in the arguments of 10/4/2006); the "second selected events" (as defined above), and only these events, are used to update the template. In other

words, the "second selected events" is not being interpreted as only the 16-beat template replacement beats, but all beats from the initialization of a template to "Natural end of Template Update".

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-23 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Although page 13 of Applicant's disclosure indicates that a template is generated from the most recent sample (i.e. "second selected events"), the Examiner was unable to find support for the negative limitation "*only* the collected second selected events". Any negative limitation or exclusionary proviso must have basis in the original disclosure. The mere absence of a positive recitation is not basis for an exclusion. Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 USC 112, first paragraph, as failing to comply with the written description requirement (See MPEP 2173.05(i)).

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-4, 7-13, 16-18, and 20-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Kim et al. (2002/0183637).

6. In regards to claims 1, 10 and 20, Kim et al. disclose a device/method that comprises generating a first template from a first set of sensed events (par. 0007), comparing the first template to a second template (par. 0008), and replacing the first template with the second in response to the template not being valid (par. 0010).

7. In regards to claims 2 and 11, Kim et al. disclose that the template update operation can be repeated indefinitely every 10 minutes to 24 hours (par. 0064), inherently enabling their invention to verify the template a third time.

8. In regards to claims 3, 4, 12, 13, 21 and 22, the invention further comprises determining whether R-R intervals are greater than a threshold (pars. 0071 and 0081) and a number of subsequent events are identified as first or second selected events (par. 0082). The examiner is interpreting the identification of the subsequent events as first or second selected events as the comparison of the template (first events) with the newly acquired beats (first or second events, depending on the comparison with the template).

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9. In regards to claims 7 and 16, cross-matches are determined between the events identified as first selected events, a predetermined number is established, and the template is generated from this group of super-threshold, predetermined number of events (par. 0108).

10. In regards to claims 8 and 17, a delay is generated if the predetermined number of events fails to generate a predetermined number of cross-matches (par. 0108).

11. In regards to claims 9 and 18, R-R intervals associated with the first events are compared to an average (par. 0071); a cross-match is computed (par. 0105) if the R-R intervals are greater (or less) than the average; and a template is generated from the events corresponding to the cross-matches (par. 0108).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 5, 6, 14, 15, 19, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. Kim et al. disclose the essential features of the claimed invention including a sense event that is not a ventricular pace event (par. 0067) and an event having an R-R interval greater than a predetermined rate of about 600 ms (par. 0071). Kim et al. do not disclose that sense events can comprise events other than those directly following a ventricular pace and sense events preceded by atrial paces by more than a threshold value. It is well known in the art that sensed events during or directly following an arrhythmia therapy are not representative of the natural electrical activity of the heart and should not be used as measurements representative of the natural electrical activity. Additionally, Kim et al. disclose excluding senses related to therapy application (par. 0067) and within a pacing threshold (par. 0081) to exclude beats that are not representative of the natural electrical activity. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Kim et al.'s invention by excluding events following a ventricular pace and sense events preceded by an atrial pace by less than a threshold duration of time to exclude beats that are not representative of the natural electrical activity of the heart. In regards to claims 6 and 15, the modified invention of Kim et al. discloses the claimed invention, but does not disclose expressly the AV threshold interval of 100 ms. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the method as taught by Kim et al. with the threshold interval of 100 ms because

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applicant has not disclosed that 100 ms provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well with the method as taught by Kim et al. because Kim et al.'s invention excludes sense events related to arrhythmia therapy, thus excluding sensed events that are not representative of the natural electrical activity of the heart. Therefore, it would have been an obvious matter of design choice to modify Kim et al.'s invention by using an AV threshold interval of 100 ms to obtain the invention as specified in the claims.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Kahelin whose telephone number is (571) 272-8688. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MWK

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1/12/07

GEORGE R. EVANISKO
PRIMARY EXAMINER
1/14/7